

### REMARKS

Entry of this Amendment is proper under 37 C.F.R. §1.116 because the Amendment places the application in condition for allowance for the reasons discussed herein; and does not raise any new issues requiring further search and/or consideration. Entry of the Amendment is thus respectfully requested.

As set forth in the Office Action Summary, claims 1, 8-10, 16-19 and 21-36 are pending. Claims 1, 8, 9, 10, 16, 17, 19, and 35 are amended herein. Applicants submit that no new matter is set forth by way of the present Amendment.

#### ***Rejections Under 35 U.S.C. § 102***

Claims 1, 8-10, 17-19, 21-36 are rejected under 35 U.S.C. 102(b) as purportedly anticipated by WO 01/38288. The Office states that formula IB on pages 5-6 of the '288 publication is an esterified fatty acid.

This rejection is respectfully traversed. It is well established that for prior art to be anticipatory, every element of the claimed invention must be disclosed in a single item of prior art in the form literally defined in the claim. See, e.g., *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 213 U.S.P.Q. 81, 90 (Fed. Cir. 1986).

The '288 publication does not recite each and every element of the present claims. Applicants note that the claims have been amended herein to recite a cetylated fatty acid without prejudice or disclaimer. The '288 publication does not disclose a cetylated fatty acid. Specifically, compound IB as referred to by the Office, is not a cetylated fatty acid.

Claims 1, 16-24, 3-36 are rejected under 35 U.S.C. 102(b) as purportedly anticipated by Musher (US Patent 4,454,159). The Office states that Musher discloses a lipid blend composition comprising tocopherol, a hydrogenated oil, lecithin and fatty acids, and isopropyl palmitate. Musher fails to disclose each and every element of the present claims for the following reasons.

Musher recites preparations for the treatment of irritated and dry skin. The formulations of Musher in columns 2-3, include glycerol trioleate, sesame oil, shortening (Crisco), and isopropyl palmeate, as noted by the Office. However, none of the elements of these formulations are cetylated or even esterified. A glycerol

triolate, as disclosed by Musher, is basically a glycerol backbone with oils. It is not a cetylated fatty acid.

In contrast, the present compositions are cetylated. The fatty acids of the present claimed invention are fatty acids esterified to cetyl alcohol. In carrying out the invention, Musher utilizes a lipid blend comprising a special combination of lipids/lipoids which include glycerol trioleate and certain other glyceride oils (particularly triglycerides). The current composition does not utilize any glyceride oils in the active formulation. It is the cetylated fatty acids that provide the benefit.

The cetylated fatty acids of the present claims have increased efficacy against diseases relating to inflammation, not present in other fatty acids. For example, EFAs act to inhibit mediators of inflammation, reduce the amount of arachidonic acid in cell membranes, reducing eicosanoid production. The fatty acids of Musher are not esterified in this way, and do not have the same properties. Further, there is not teaching or suggestion in Musher to lead one of skill in the art to cetylate the recited fatty acids, as in the presently claimed invention.

In light of the above, Applicants request that the rejections under 35 U.S.C. § 102 be withdrawn.

***Rejections Under 35 U.S.C. § 112***

Claims 1, 8-10, 16-19, 21-36 are rejected under 35 U.S.C. 112, first paragraph because the specification, while being enabling for cetylated fatty acids, does not reasonably provide enablement for all esterified fatty acids. In the interest of expediting prosecution and without acquiescing in the rejection, Applicants have amended the present claims to recite cetylated fatty acids. The claims are further amended to recite arthritis and periodontal disease. Thus, Applicants submit that this rejection is obviated.

**CONCLUSION**

It is respectfully submitted that all rejections have been overcome by the above amendments. Thus, a Notice of Allowance is respectfully requested.

In the event that there are any questions relating to this amendment or the application in general, it would be appreciated if the Examiner would contact the undersigned attorney by telephone at (703) 836-6620 so that prosecution of the application may be expedited.

Respectfully submitted,

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